

REMARKS

Applicant thanks the Examiner for the detailed Office Action dated 29 January 2007.

Applicant respectfully requests reconsideration of the present application in view of the reasons that follow.

Claims 1-47 were pending in the application. Claims 2-3, 6, 8-11, 18, 23, 26-27, and 40-44 are requested to be cancelled without prejudice or disclaimer. Claims 1, 4-5, 7, 12-17, 19-22, 24, 28-39, and 45-47 are currently being amended. Claims 48-60 are being added. After amending the claims as set forth above, claims 1, 4-5, 7, 12-17, 19-22, 24-25, 28-39, 45-60 are now pending in this application.

For simplicity and clarity purposes in responding to the Office Action, Applicant's remarks are primarily focused on the rejections applied to the independent claims (i.e., claims 1, 28, and 45-47) as outlined in the Office Action with the understanding that the dependent claims are patentable for at least the same reasons (and in most cases other reasons) that the independent claims are patentable. Applicant expressly reserves the right to argue the patentability of the dependent claims separately in any future proceedings.

Claim Rejections – 35 U.S.C. § 102***Independent Claims 1, 45, and 46***

On page 2 of the Office Action, independent claims 1, 45, and 46 and various dependent claims were rejected under 35 U.S.C. § 102(b) as being unpatentable over U.S. Patent No. 6,179,863 to Kensey et al. Applicant respectfully traverses the rejection. Kensey et al. does not identically disclose the subject matter recited in independent claims 1, 45, or 46.

Applicant respectfully submits that Kensey et al. does not identically disclose the combination of elements recited in independent claims 1, 45, or 46, as amended. For example, independent claim 1, as amended, recites a "vascular insertion assembly" including, among other elements, a "first distal hole located at a distal end of the vascular insertion assembly," a "first

indicator located at a proximal end of the vascular insertion assembly, the first indicator being in fluid communication with the first distal hole,” a “second distal hole located at the distal end of the vascular insertion assembly,” and a “second indicator located at the proximal end of the vascular insertion assembly, the second indicator being in fluid communication with the second distal hole,” which is not identically disclosed by Kensey et al.

Also, independent claims 45 and 46, as amended, each recite a “vascular insertion assembly” including, among other elements, a “distal end where a first distal hole and a second distal hole are located” and a “proximal end where a first indicator and a second indicator are located” wherein “the first distal hole is in fluid communication with the first indicator and the second distal hole is in fluid communication with the second indicator,” which is not identically disclosed by Kensey et al.

For the above reasons, Applicant respectfully submits that independent claims 1, 45, and 46 and the claims which are dependent thereon are not anticipated by the cited reference and are patentable.

Claim Rejections – 35 U.S.C. § 103(a)

Independent Claims 28 and 47

On page 2 of the Office Action, independent claims 28 and 47 and various dependent claims were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kensey et al. Applicant respectfully traverses the rejection. The cited reference does not disclose, teach, or suggest the subject matter recited in independent claims 28 or 47.

Applicant’s understanding of the Patent Office’s obviousness argument is as follows: (1) Kensey et al. suggests the combination of the sheaths from Figs. 27 and 31 with the dilator of Fig. 29 in lines 25-48 of column 11, (2) one of skill in the art is capable of adding a second drip hole when the structures are combined, and (3) the modification would increase the versatility of the components by allowing the user multiple modes of identifying blood vessel location.

Applicant respectfully submits that the Patent Office has failed to establish a *prima facie* case of obviousness because: (a) Kensey et al. does not teach the combination of the sheaths as asserted by the Patent Office and, in fact, teaches away from such a combination (b) the fact that Kensey et al. can be modified to result in the claimed subject matter is insufficient to establish a *prima facie* case of obviousness in the absence of a teaching, motivation, or suggestion to make such a modification (see MPEP § 2143.01(III)), and (c) the motivation of “allowing the user multiple modes of identifying blood vessel location” has no basis in Kensey et al. or anywhere else. Each of these reasons is explained in detail as follows.

Applicant respectfully submits that Kensey et al. does not teach or suggest combining the sheaths from Figs. 27 and 31 with the dilator of Fig. 29, and, in fact, Kensey et al. teaches away from such a combination. The passage relied on by the Patent Office does not suggest making the asserted combination. The passage in question reads:

The positioning of the introducer sheath 28 utilizing either of the devices 300 or 400 or the positioning of the introducer sheath 28' utilizing the obturator 600 is similar to that described with reference to the device 200.

This passage makes it clear that the introducer sheath 28', shown in Fig. 31, utilizes the obturator 600. There is no teaching or suggestion in this passage to combine the introducer sheath 28' with any of the other dilators. As for introducer sheath 28, at first blush it would appear that any introducer sheath 28 can be used with either dilator 300 or 400. However, a closer examination of the specification reveals that the introducer sheaths shown in Figs. 27 and 29 are both identified using reference numeral 28 even they each have a unique configuration that makes one incompatible with the other's dilator. For example, the dilator 400 cannot be used with the sheath 28 from Fig. 27 because the port 304 would be blocked by the dilator. Also, the dilator 300 cannot be used with the sheath 28 from Fig. 28 because the recess 302 in the dilator would be blocked by the sheath 28 thereby preventing the resulting device from providing any feedback on the location of the blood vessel. The conclusion to be drawn from this analysis is that the above quoted passage simply uses the generic term “introducer sheath 28” to refer to the respective embodiments of the introducer sheaths shown in Figs. 27 and 29 that are compatible

with the particular dilators 300 or 400. There is no teaching or suggestion in this passage to combine the introducer sheath 28 from Fig. 27 with the dilator from Fig. 29.

Not only is there no teaching or suggestion to combine the insertion sheaths and dilators in the manner asserted in the Office Action, Kensey et al. teaches away from such a combination. Kensey et al. teaches away from combining the sheath from Fig. 27 with the dilator from Fig. 29 by explaining that the sheath 28 shown in Fig. 27 has a port 304 and the dilator 300 has a recess 302 to allow blood to flow through the port 304 in the sheath 28, up along the recess 302 and out the sideport 28D (see col. 10, lines 24-53). In contrast, the dilator 400 does not have a recess 302 so that if the insertion sheath 28 from Fig. 27 was used with the dilator 400, the hole 304 wouldn't lead to anything – there would just be a nonfunctional hole in the side of the insertion sheath. To the extent the Patent Office disagrees, the Patent Office is required to make particular findings regarding why the skilled artisan, viewing each reference as a whole and with no knowledge of the claimed invention, would have combined the sheath from Fig. 27 of Kensey et al. with the dilator from Fig. 29 even though doing so would create a sheath with a nonfunctional hole in the side. See In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (holding that the Patent Office must make “particular findings . . . as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.”).

Kensey et al. teaches away from combining the sheath from Fig. 31 with the dilator 400 from Fig. 29 by explaining that the passageway 402 in the dilator 400 and the passageway 502 in the insertion sheath 28' both end at the sideport 28D. Kensey et al. teaches away from such a combination because there is no added benefit to using both of these passageways 402, 502 since they both end at the same sideport 28D and do the same thing (i.e., locate the blood vessel). The result of combining the sheath from Fig. 31 with the dilator 400 is to increase the complexity of the device without any added benefit. To the extent the Patent Office disagrees, the Patent Office is required to make particular findings regarding why the skilled artisan, viewing each reference as a whole and with no knowledge of the claimed invention, would have combined the sheath from Fig. 31 of Kensey et al. with the dilator from Fig. 29 even though doing so would

create an even more complex device without providing any additional benefit. See In re Kotzab, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000) (holding that the Patent Office must make “particular findings . . . as to the reason the skilled artisan, with no knowledge of the claimed invention, would have selected these components for combination in the manner claimed.”).

Applicant respectfully notes that even if the subject matter of Kensey et al. was combined in the manner asserted in the Office Action, the resulting device would still not include two proximate holes or ports (or indicators in the case of some of the other independent claims). Therefore, Kensey et al. does not teach or suggest all of the claim limitations. The Patent Office seems to acknowledge this weakness and attempts to overcome it by asserting that “one of skill would be **capable** of providing a second drip hole” in the combined structure. This is improper because the fact that Kensey et al. **can** be modified to result in the claimed subject matter is insufficient to establish a *prima facie* case of obviousness in the absence of a teaching, motivation, or suggestion to make such a modification. The MPEP at Section 2143.01(III) explains that the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. In re Mills, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). Applicant also respectfully submits that the motivation of “allowing the user multiple modes of identifying blood vessel location” has no basis in Kensey et al. or anywhere else.

Applicant respectfully submits that the subject matter recited in independent claims 28 and 47 and the claims which are dependent thereon, considered as a whole, would not have been obvious to a person of skill in the art and are patentable. Accordingly, Applicants request that the Patent Office withdraw the rejection of these claims under 35 U.S.C. § 103(a).

New Claims

Applicant has added new claims 48-60. Applicant submits that these claims are allowable over the cited art.

Applicant respectfully submits that the present Application is in condition for allowance. Applicant requests reconsideration and allowance of the pending claims. The Examiner is invited to contact the undersigned by telephone if the Examiner needs anything or if a telephone interview would advance the prosecution of the present application.

Applicant respectfully puts the Patent Office and all others on notice that all arguments, representations, and/or amendments contained herein are only applicable to the present patent application and should not be considered when evaluating any other patent or patent application including any patents or patent applications which claim priority to this patent application and/or any patents or patent applications to which priority is claimed by this patent application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 08-2623. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 08-2623.

Respectfully submitted,

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